

Please add new claims 28 and 29 as follows:

*Sil D3* 28. A system to detect likely precancerous and cancerous cells in a cell population, said system comprising:

- c8*
- (a) brush means to collect said cell population,
  - (b) analytical apparatus comprising imaging apparatus for imaging said cell population,
  - (c) said imaging apparatus morphologically selecting individual atypical cells from said cell population, and
  - (d) means to conduct DNA ploidy quantization of said selected individual atypical cells.

29. The system of claim 28, wherein said imaging apparatus comprises means to select the most suspect atypical cells from said cell population.

#### REMARKS

Careful consideration has been given the above-identified Official Action, and reconsideration of this application, as amended, is respectfully requested.

The drawings had been objected to. Amendments have been made to the drawings, Figures and specification for the purpose of consistency. Proposed drawing corrections correcting diagrams 1-3 to be identified as Figs. 4-6 is enclosed herewith.

Claims 16-21 and 23-37 have been rejected under 35 USC 112. Independent claim 16 has been rewritten and replaced with new claim 28, and it is believed the objections to claims 16-21 and 23-27 have been addressed.

Further, with regard to the originally pending claims 16-21 and 23-27, claims 16 and 17 have been cancelled and replaced with new claims 28 and 29. Claims 18, 19, 23, 24, 26 and 27 have been amended.

Additionally, claims 24-27 were objected to because it was not clear how the brush cooperates with the apparatus. This has been remedied with new claim 28 which is directed to a system to detect likely precancerous cells from a cell population in which the brush collects the cell population.

The claims were rejected, primarily over the prior art reference to Rutenberg, 5,740,270.

The Examiner states on page 5 of the Office Action that the Rutenberg reference '270 discloses that the system is capable of DNA ploidy analysis. Reference is made to column 4, lines 15-40. In this regard, the Examiner is incorrect since the prior art Rutenberg patent does not teach, show or suggest conducting a DNA ploidy analysis. At best, as found in column 14, lines 28-36, the prior art Rutenberg reference suggests that morphological algorithms based on features relating to DNA ploidy analysis or color may be used to classify cells. In other words, the prior art Rutenberg reference does not conduct a DNA ploidy analysis of selected cells on a cell by cell basis, but it is directed to conducting morphological analysis looking for suspect cells. That morphological analysis is based on "color or features relating to DNA ploidy analysis", and in fact there is no DNA ploidy analysis conducted on selected cells.

This is an important distinction because if the prior art actually taught conducting a DNA analysis to help select precancerous and cancerous cells as part of its teaching, it would be terribly problematic because if the DNA ploidy analysis was conducted on a cell by cell basis as an initial step, it would produce enormous medical inaccuracies because a large number of cells would be rejected, which may be cancerous and do not exhibit the DNA ploidy analysis sought after. In other words, not all cancerous cells exhibit that sought to be determined in a DNA ploidy analysis, and if one were to use DNA ploidy analysis as a selector of precancerous or cancerous cells, there would be grave and serious inaccuracies.

The prior Rutenberg reference does not show, suggest, teach or disclose first selecting atypical cells from a cell population, and then after selecting those atypical cells (which are selected for their atypicality because of characteristics tending to be cancerous or precancerous) which are thereafter individually analyzed cell by cell for DNA ploidy as a further refinement of those atypical cells already identified for their carcinogenic tendency.

The remaining references have not been specifically addressed as they do not in any way show, suggest or teach applicant's novel invention as currently set forth and identified in this pending application.

Claim 28, the primary independent claim, specifically calls for a brush to collect the cell population, analytical apparatus which comprises imaging apparatus to image the cell population and morphologically select individual atypical cells and thereafter conducting a DNA ploidy quantization of the selected individual atypical cells. Such a system is neither shown, suggested, nor disclosed in the prior art, taken alone or in combination.

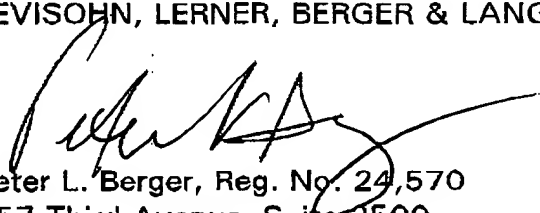
This Amendment has addressed all of the outstanding rejections based on drawings, 35 USC 112 and on prior art.

This is a response after Final, and this response is submitted with a request for a two month extension. It is hoped that an advisory action on this will be issued before December 30<sup>th</sup> so that appropriate action can be taken without the passage of an additional month.

The Examiner's prompt reconsideration of this Amendment would be greatly appreciated in view of the limited time currently available.

Respectfully submitted,

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**AMENDED CLAIM MARKED UP TO SHOW ALL THE CHANGES**

18. (Amended) The system of claim 28 17, wherein the locations of said selected atypical cells exhibiting both atypical morphology and cytometry are retrieved by said computer for DNA ploidy analysis by a pathologist on a cell by cell basis.

19. (Twice Amended) The system of claim 18, wherein said [computer] system plots a histogram based of the DNA ploidy of said cell population.

23. (Twice Amended) The system of claim [18] 28, comprising the further examination of said selected atypical cells with molecular diagnostic techniques.

24. (Amended) The system of claim [18] 28, wherein said cell population is retrieved from epithelial tissue, wherein said [further comprising a] brush means which removes said cell population from said tissue, said brush removing cells from at least two layers of said epithelial tissue.

26. (Amended) The system of claim 24, wherein the location of said selected atypical cells [exhibiting both atypical morphology and cytometry] are retrieved by said completer for DNA ploidy analysis [by a pathologist] on a cell by cell basis.

27. (Amended) The system of claim 24, comprising the further examination of said selected atypical cells with molecular diagnostic techniques.